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09/870,321	05/30/2001	Volker Lehmann	32226.4	7637

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,321	LEHMANN, VOLKER	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 11-14 are moot in view of the fact the claims have been canceled.

As to claim 15 referenced as new claim 1, on page 9 of the remarks, applicant states Pelc et al. does not discuss taking up a first medium without taking up a second in an automated controlled fashion. Such an assertion is not commensurate in scope with the claimed apparatus. Such function is stated in the preamble and is directed to intended use.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

The recitation that the device is for taking up a first medium .... without taking up a second medium has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951)

Applicant further asserts Pelc et al does not disclose a diaphragm with at least one port at the lower end of the pipette. This is a new limitation not previously incorporated in any of the previous claim and will be addressed accordingly herein:

Claim 15 is interpreted as a device requiring a pipette having lower end; a diaphragm located at the lower end, the diaphragm having at least one port of at least one diameter, and wherein a part of the diaphragm comprises a biological binding

material, a pump coupled to the pipette that is capable of applying a negative pressure; and pump controller that controls the level of negative pressure.

As stated above how applicant intends to use the device is irrelevant to the structure of the device. The element which applicant refers to as a diaphragm may be also considered as a filter or membrane with a pore. There is no specific location required for the binding material. Hence the element could be coated, lined, or imbedded with the material. The pump is only required to be able to produce negative pressure (vacuum pump). The controller controls the pump. The mentioning of a critical pressure within claim 15 is irrelevant. The claim does not specify nor define any particular critical pressure. What critical pressure? Therefore any pump can be said to maintain a level below a critical pressure.

Applicant states "This passage only includes a general statement with regard to a surface tension, but it fails to disclose a teaching with regard to a predetermined controlling of the pressure which is used to take up the liquid. In contrast thereto, the invention provides a controlling of the pressure which is used to take up a first medium and provides an exact controlling instruction, namely that the "critical pressure within the pipette is determined according to the following rule (equation):"

In view of the apparatus claim the argument is based upon intended use. Furthermore, the controller is not specified as being governed by such an equation in the claims.

The rule or governing equation is well-known in the art as the Laplace equation of capillarity (as evidenced by the documents provided). The equation is the basis of

describing, characterizing, and explaining the phenomena of capillary penetration or spreading of liquids on surfaces or in or through conduits. The critical pressure is an inherent pressure that is present with fluids that must be overcome for any type of fluid movement to occur during an aspiration process.

Applicant further states Pelc et. al. is not directed to analysis of an analyte. In view of the apparatus, the prior does not have to be directed to the same use to establish structural equivalence. Furthermore analysis is only mentioned in dependent claims 20-21 and 30.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Both claims 15 and 26 were amended to incorporate limitations directed to a diaphragm. The claims recite

a diaphragm located at the lower end of the pipette, the diaphragm defining at least one pore, the at least one pore having at least one diameter, and wherein at least a part of the diaphragm further comprises biological material for binding the molecules contained in the first medium as the first

medium is drawn therethrough

Applicant has not pointed out where the new claims are supported by the specification. In a cursory review of the application, the examiner has failed to locate support of such an amendment. The primary discussion of the diaphragm appears to be located on pages 11-13 of the specification filed 7/30/04. Applicant is hereby invited to provide support for such a claim or remove the material therefrom.

Furthermore, while there is support for the device comprising a pump 104, the examiner fails to locate within the specification where a pump controller is included along the pump and is programmed or automatically controls the pump as asserted by applicant.

Furthermore claim 19 is also directed to new matter. There is no support within the specification or drawings for a plurality pores having different diameters nor a single pore varying in diameter throughout its dimensions (see also 112, second paragraph below).

Claims 20, 21, and 30 suggest the diaphragm is capable of performing some type of analysis. There is no support found in the specification for such a claim. There is a mentioning of an analysis chip 206 having the ability of performing analysis. The neither specification nor drawings provide support for a diaphragm comprising an analysis chip or vice versa. In figure 4, the diaphragm is shown alone. In the specification the elements 206, 207 are described separately and are shown as such the figures.

It should be noted claims 20 and 21 are considered further limiting as a diaphragm and analysis chip respectably are capable of analysis. The mentioning of the first medium adds no patentable weight to the claims (as stated above).

The examiner further fails to locate where applicant discloses performing a method as specified in claims 26-34, the examiner hereby requests applicant specify where the claimed method is supported and the steps as claimed are specified to ensure proper support is within the specification. Such as where is step of controlling pressure and dispensing the first medium?

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant canceled all of the previously pending claims. Therefore, the previous 112 issues were not addressed. However a number of those 112 issues also exist within the new claims.

As to claim 15 it is unclear what elements consider as structure of the device. The first and second mediums are not claimed as elements of the invention. It's not clear what the first and second mediums are. A medium can be gas, liquid, or solid. The environment in which the mediums are located are not specified. The mediums may or may not be in the same phase. The examiner only points out this issues as to illustrate how the claim is unclear. This is not to suggest the such clarification would

result in allowability of the claims. Again the mediums only represent substances which applicant intends for the device to be used with. It is well known in the art that a controller and pump may be employed to aspirate a single fluid from a container without aspirated a second (such as air). The ability of a controller to aspirate a specific amount of a fluid of from a container would be considered meeting the limitation of the controller as claimed, for no second fluid is aspirated.

It is unclear what one considers "a reduced pressure". Reduced as compared to what? The term reduced is in relevance to some standard. There is no specified standard for one to determine what is reduce. It appears as if the more accurate term would be negative pressure.

All claims directed to the critical pressure are unclear. For applicant does not specify a critical pressure of any particular thing. As such it can be said any controllable pump can function below the critical pressure of something. While the examiner assumes applicant is referencing a critical pressure of one of the two mediums mentioned. As previously stated, the mediums are not elements of the invention.

As to claims 18 and 19 it is unclear what is meant by constant and variable. Does constant mean 1 pore has one diameter throughout its length or a plurality of pores all have a single diameter which is the same.

As to claim 19, it is unclear what is meant by variable.

In view of page 11, the pore size is referenced in terms of diameter rather than radius as in the claims. For consistency the examiner suggests the claims should be amended to reference the diameter. It appears as if constant means 1 diameter

throughout the length of 1 pore and in the case when a plurality of pores are presence each pore has the same diameter throughout.

As to the term variable it appears as applicant meant to claim the single diameter of a single pore or a plurality of pores with the same diameter may vary be within the specified range as disclosed.

Claim 22, is directed to a process limitation or how applicant intends to use the device.

Claims 24 and 25 are not further limiting for they are directed to specifying the phases of the mediums, which are not structural components of the device.

As to claim 26, it is unclear how the method is performed for the claim does not establish how the mediums are related to one another. Are the mediums in a single container in the same space? Are the mediums in separate containers or in the same container but separated by some structural barrier such as a membrane? Are the mediums in the same container and are in immiscible so a boundary layer or interface is established cause one medium to float on top of another? Since no particular arrangement is required, aspirating a fluid or solid from one container without ever aspirating anything from a second container using the device as claimed would meet the limitations. In the previously mention scenario it wouldn't matter what the phases or either substance is nor the critical pressure of anything the fact is one substance would be aspirated without aspirating another and the pressure for the aspiration would be lower than a critical pressure of something.

It is unclear if the controlling step occurs after the taking up step. It appears as if the last paragraph of the claim should read: controlling the pressure within the pipette during the taking up step to ensure that the second medium is not taken up.

It is unclear how applicant is intending further limit the device and method respectively with claims 17 and 28.

The equation of claim 17 and 28 states shows how a critical pressure is calculated. It is does not add any further structure to the claimed elements. Furthermore the equation is dependent upon unclaimed elements. Claim 28 does not add a further step nor limit a previous step. Any device meeting the limitation of the independent claim can be said to have a pore which would follow the equation. The equation has no bearing on how the device or method or performed for it is not related claimed in the a manner in which it is related to or further limits an element or method step.

Claim 29 appears to be redundant for is merely recites what is included claim 26.

It is unclear where the steps of claims 30 and 33 occur in relevance to the previously recited steps. It appears as if step of claim 30 would occur after the fluid passes through the diaphragm. Claim 26 does not specify the medium passes through or enters the diaphragm as to establish that molecules are actually bound in the diaphragm. As such it appears as if claim 26 or should be amended as such, for no analysis can occur without such a step occurring.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the a diaphragm comprising and analysis chip and a variable pore radius, and the gas/liquid medium arrangements must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to because element 405 does not designate a lower end and 404 is not an arrow. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 15-18 and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelc et al. in view of Tajima US 5,895,631.

Pelc et al. disclose a microvolume liquid handling system.

In one aspect of the invention, the pressure in the dispenser (such as in dispenser 212 (pipette) of FIG. 7) is reduced as the result of reducing the system liquid reservoir (214 in FIG. 7) pressure. The valve (242 in FIG. 7) is closed, and then the nozzle of the dispensing unit can be immersed in the transfer liquid to aspirate a small quantity of the transfer liquid into the dispenser. For example, when gauge pressure in the dispenser reaches minus 30 millibars, submersing the nozzle in the transfer liquid may draw a sufficient amount of liquid to increase the gauge pressure to minus 15 millibars. It should be noted that the dispenser does not aspirate air unless the surface tension in the nozzle is exceeded by the negative gauge pressure. In the preferred embodiment system using dimethyl sulfoxide, the negative gauge pressure to about 45 millibars does not produce air aspiration into the nozzle. (column 15, lines 13-22).

The above recited aspect of the invention encompasses all the steps and concepts of the instant invention as recited in the above mentioned claims.

As seen in Figure 7, the device may comprise liquid reservoir 214 receives system liquid 20, typically deionized water or dimethyl sulfoxide (DMSO), through an intake tube 216 which contains a cap (not separately shown). The cap on the intake tube 216 is removed to enable the sealed system liquid reservoir 214 to receive system liquid 20 when the cap is off and seals the system liquid reservoir 214 shut when the cap is on so that the system liquid reservoir 214 can be maintained at a desired pressure. Pressure in the system liquid reservoir 214 is maintained by a pressure control system 218, through pressure control tubing 220. The pressure control system

218 includes an electrically controlled pump (pump/pump controller connected to capillary/pipette device 212 are required in claim 6) capable of accurately increasing or decreasing pressure in the system liquid reservoir 214. A pressure sensor 222 mounted on the system liquid reservoir 214 senses pressure in the system liquid reservoir 214 and transmits an electrical signal indicative of that pressure to a system controller 224 through electrical conductor 226. The system controller 224 contains a digital signal processor board and other electronics(not shown) which enable monitoring of various electrical signals, execution of control software code, and control of the microvolume liquid handling system 210. The system controller 224 electrically controls the pressure control system 218 through an electrical conductor 228 to adjust the pressure of the system liquid 20, and correspondingly, the pressure of the transfer liquid 24 232.

Further more the plurality of dispensers/pipette devices are arranged in a plate (claims 13) which may be positioned by a robotic system.

Pelc et al. do not teach the employment of a diaphragm within the capillary device.

Tajima discloses a liquid processing method making use of a pipette device which sucks a liquid containing a target high molecular substance from inside of a vessel through a chip detachably set on a sucking port or a discharging port of a liquid sucking/discharging line and transfers this liquid or target high molecular substance to the next target processing position for the purpose to execute such works as quantifying, separating, taking out, pipetting, clarifying, condensing, and diluting a liquid or a target high molecular substance contained in a liquid.

The device may employ a filter to screen out substances from blood is provided in the first stage of the chip and a filter holder with a silica membrane filter to capture DNA.

Although the device may include multiple filters each filter has a constant diameter.

It is further discloses analysis may be conducted after the components are separated.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the modified teachings of Pelc et al. by providing the chip analysis pipetting system of Tajima in the modified device in order to perform simultaneous analysis of each sample which provides for time reduction in processing a large number of samples.

Pelc et al. does not specify using a gas a first medium and liquid as a second medium.

However it would have been obvious to one of ordinary skill in the art at the time of the invention recognize that a gas such as air may be aspirated at a reduced pressure without taking up a liquid in order to allow the air/gas to permit the drying of a capillary after it has been washed.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gratzl, Miklos et al.; Gierde, Douglas T. et al.; Sakurai, Toshinari

et al.; Ingenhoven, Nikolaus et al.; Aysta; James E. et al.; Aysta; James E. et al.; Aysta; James E. et al.; Bjorkman; Rune; and Iriguchi; Norio disclose fluid separation devices.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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